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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Draft Guidance for Industry on Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics (Docket No. FDA-2013-N-1430)

Dear Sir or Madam:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to submit these comments in response to the Food and Drug Administration's (FDA) Draft Guidance for Industry on Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics (Draft Guidance).[1] PhRMA is a voluntary, non-profit association that represents the country's leading pharmaceutical research and biotechnology companies. PhRMA members are dedicated to developing medicines that allow patients to live longer, healthier, and more productive lives. In 2013 alone, PhRMA members invested an estimated $51.1 billion in the research and development of new medicines.

PhRMA and its members understand the importance of conveying reliable and timely information about medicines to healthcare professionals and patients, and we are committed to helping assure that all communication about medicines is truthful and not misleading.[2] The extensive and growing use of online media and new technology for healthcare communication by both FDA and the Department of Health and Human Services demonstrates the promise and value of such media to benefit patients.

[1] 79 Fed. Reg. 2,449 (Jan. 14, 2014).
[2] To help accomplish these goals, PhRMA has created its "Code on Interaction with Healthcare Professionals" and "Guiding Principles on Direct to Consumer Advertisements About Prescription Medicines." PhRMA was also an active participant in FDA's two-day public meeting on this topic in November 2009 and provided input in response to Docket No. FDA-2009-N-0441 following the meeting.

I. Executive Summary

PhRMA welcomes FDA's Draft Guidance as an important step toward helping to ensure the availability of timely, accurate and accessible information about medicines. Though many challenges remain before this goal is fully attained,[3] PhRMA appreciates FDA's initial efforts to address questions relating to online communication about medicines through interactive social media in its Draft Guidance.

The public health will be best served by clear policies for interactive social media that both encourage open and frank dialogue about truthful, scientifically accurate information and do not unduly chill health care communication. PhRMA member companies have the most complete and up-to-date information about the medicines they research, develop and manufacture. Given the extraordinary growth of the Internet as a source of health information—and the enormous amount of inaccurate and non-regulated information about medical products online—FDA should avoid chilling manufacturers' responsible communication of medical information about their products and should allow manufacturers to take advantage of the same technologies that FDA and the White House use, including blogs, video, search, and social networking sites such as Twitter. Moreover, any guidance document or other policy statement issued by FDA should be consistent with the principles and limitations of the Federal Food, Drug and Cosmetic Act (FDCA) and the First Amendment.

PhRMA and its member companies would like to highlight two fundamental concerns with the Draft Guidance. First, the Draft Guidance assumes that a biopharmaceutical manufacturer can be held accountable for content written by third-parties on third-party web sites if the company merely "influences" the third-party. This premise is overbroad and is inconsistent with the FDCA. Put simply, third-party statements not caused or controlled by a manufacturer do not fall within the statutory or regulatory scope of FDA's authority to regulate promotional labeling or advertising. Second, the Draft Guidance erroneously assumes that all manufacturer statements about prescription medicines on social media constitute promotional labeling or advertising. This expansive interpretation of labeling and advertising adopted in the Draft Guidance could chill truthful and non-misleading communication protected by the First Amendment. Thus, it is critical that FDA address these fundamental issues in the Final Guidance.

In addition to identifying and discussing these two fundamental issues, PhRMA provides additional suggested revisions for the Final Guidance in these comments. In the Final Guidance: (1) FDA should confirm its commitment to protecting online scientific exchange using social media; (2) FDA should require only quarterly activity reports rather than monthly activity reports; (3) FDA should confirm that it understands the fluid nature of interactive social media and will exercise its enforcement discretion accordingly; (4) FDA should allow firms to satisfy the submission requirements for interactive social media posted on restricted sites by providing FDA with log-in credentials to those sites; and (5) FDA should clarify that the guidance only applies to interactive social media.

[3] Although the Draft Guidance does not address other challenging issues raised by patients' increasing use of social media, such as adverse event reporting, providing safety information in the context of social media, and correcting misinformation on social media, PhRMA understands FDA plans to provide additional thinking on such issues in the near-term.

II. The Final Guidance Should Recognize That Manufacturers Are Responsible Only For Third-Party Statements They Cause or Control

PhRMA believes that a biopharmaceutical manufacturer is accountable only for a web site or for other content that it causes or controls, which should be defined as content that is controlled entirely by the manufacturer or its agents and that the manufacturer or its agents are authorized to edit or delete in the manufacturer's sole discretion. This understanding of accountability is supported by the FDCA and its implementing regulations and should be reflected in FDA's Final Guidance.

A. The Draft Guidance's "Influence" Test Is Overbroad and Not Supported by the FDCA

The Draft Guidance suggests that mere "influence" is sufficient to hold a manufacturer accountable for third-party statements or user generated content (UGC), and further, that such third-party statements or UGC thus constitute "advertising" or "labeling" subject to FDA's postmarketing submission requirements. These views are not supported by the FDCA.[4] Accordingly, for the reasons discussed below, FDA should eliminate the "influence" test for determining whether companies should be accountable for third-party communications online.

Although Section 301 of the FDCA enumerates prohibited acts, both the commission and "causing" of which are prohibited, it does not purport to reach the "influence" of actions that could otherwise be considered prohibited.[5] The nebulous term "influence" inappropriately sweeps in third-party statements not caused or controlled by the manufacturer. "Influence," which is commonly defined as "[a] power indirectly or *intangibly affecting* a person or event,"[6] provides an insufficient basis for attributing third-party statements to a manufacturer, much less treating third-party statements as "advertising" or "promotion." The interactive and interconnected nature of social media separates it from traditional media and also amplifies the overbreadth of the standard set forth in the Draft Guidance. For example, if a firm invites all comments about its prescription medicine on a firm owned bulletin board, will it be deemed to have influenced all of the subsequent posts? If a firm acknowledges users' posts or thanks users for their comments on a firm-owned site, will a firm be deemed to have influenced potential user

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[4] 21 U.S.C. § 301 *et seq.*

[5] FDA's interpretation of "causation" in this context must be appropriately tailored to comply with the First Amendment, otherwise it would be subject to the same concerns as FDA's overbroad "influence" test discussed below. The Internet and social media are an "unlimited, low-cost capacity for communication of all kinds," *see Reno v. ACLU*, 521 U.S. 844, 870 (1997), and the content-based regulation of speech on social media announced in the Draft Guidance, potentially enforced with the threat and stigma of criminal convictions, mandates higher scrutiny, *id.* at 871-72. Moreover, there is no justifiable government interest in chilling the speech of a manufacturer providing a forum to discuss health information, while similarly situated entities that do not manufacture pharmaceuticals may enjoy such rights without such burdens. *See Sorrell v. IMS Health*, 131 S. Ct. 2653, 2663-64 (2011) (striking down content and speaker based restrictions focused solely on pharmaceutical marketers disseminating information for pharmaceutical marketing purposes).

[6] Webster's II New College Dictionary 582 (3d ed. 2005) (emphasis added).

generated comments in response? Indeed, given the ambiguous nature of the term "influence," what is the likelihood that a firm could make a statement or actively participate on social media in communication about one of its medicines *without* being perceived to somehow indirectly or intangibly affecting someone's response?

The Draft Guidance's examples applying the "influence" test confirm its overbreadth. The Draft Guidance states that "if a firm collaborates, or has editorial, preview, or review privilege [over posted content], then it is responsible for its promotion on the site and, as such, that site is subject to submission to FDA to meet postmarketing submission requirements." In addition, in Example 3, the Draft Guidance states that a firm is responsible for third-party content if it "makes suggestions" about the placement of its promotional content on a third-party site because the firm "influenced the placement of its promotion within the third-party site" and thus it must submit to FDA "the promotion, along with the surrounding pages. . . . in order to fulfill the postmarketing submission requirements."

Neither "preview or review" privilege nor suggestions regarding the placement of promotional material are sufficient cause to attribute third-party statements to a manufacturer, unless such privileges are so extensive as to permit the manufacturer total control of such third-party statements in the manufacturer's complete discretion. Preview or review privilege has never been considered a deciding factor in determining whether content is independent from a supporting company.[7] Likewise, a firm should not be held responsible for third-party content on "surrounding pages" merely because it directs the placement of promotional material on a third-party site. In fact, because of the unique features of interactive social media, the content of pages that surround a given page frequently changes without any knowledge or input by the firm. For example, both Facebook and Twitter are configured to show content that the user has "liked" or "followed" recently. It is impossible for a firm to know what content a third-party user will "like" or "follow" in the future, and therefore, the firm should not be held responsible for the content on the "surrounding pages." Indeed, a firm is not held responsible for the content that surrounds a digital banner advertisement placed on a web site merely because it controlled the placement of that banner advertisement. For example, a firm advertising an asthma drug on WebMD may require that its advertisement for asthma only appears in the asthma section of the site, or as a banner on the top of the page rather than the side or bottom. Similarly, a firm providing promotional materials using traditional media is not responsible for content on the "surrounding pages" of the promotional material in a magazine simply because it specifies that its advertisement be placed in a particular location such as on the inside cover.[8]

Furthermore, if a firm provides direction on where promotional material should *not* be placed, such as next to editorial content that may be inappropriate or inconsistent with the firm's standards (e.g., alcohol or tobacco), the firm should not be held responsible for the surrounding third-party content. A firm might legitimately have a need to oversee the placement of its content to ensure that materials would be presented or function as intended. Third-party

[7] Prior FDA guidance in a related field, for example, does not indicate that a firm with "preview or review privilege" over supported content is responsible for the content. *See Guidance for Industry: Industry–Supported Scientific and Educational Activities,* 62 Fed. Reg. 64,093, 64,096–99 (1997) (hereinafter, "CME Guidance").

[8] Some sites may be partitioned to separate content from a wide variety of sources. For example, a firm may create a YouTube page, but this should not render a firm responsible for other users' related YouTube pages or advertisements that YouTube may choose to place on portions of the page that are owned or controlled by YouTube.

sites may also have varying fees for promotion depending on the location of the content (e.g., a higher fee may be charged for content appearing on a home page), and firms may need to select the placement of the content in order to advertise on a particular site. The only appropriate situation where a firm should be held responsible for the content of "surrounding pages" is if a firm has control over the precise placement of the advertisement while also *knowing* the specific adjacent fixed content.

The breadth of the proposed "influence" concept would sweep in materials that could not properly be considered within the scope of FDA's regulation of "labeling" and "advertising." The FDCA defines "labeling" as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."[9] Courts have held that material does not need to be physically attached to be considered as "accompanying" the article.[10] "On the other hand, labeling does not include every writing which bears some relation to the product. . . . and, if the statutory purpose is to be served, it must be drawn in terms of the function served by the writing."[11] It has thus long been established that materials constitute "labeling" under the FDCA only where they are designed for use in the distribution and sale of the product, and related in such a way to the product to be considered part of an integrated distribution program.[12] The Draft Guidance essentially reads the "accompanying such [drug]" proximity requirement out of the Act by concluding that third-party comments on third-party web sites may "accompany" a manufacturer's drug. Likewise, advertising, which is not defined by the FDCA, cannot reasonably be understood to encompass third-party statements simply because those statements reference a drug or are made on a forum controlled by the manufacturer. The common meaning of the term envisions promotion for commercial sale, a motivation held only by the drug's manufacturer or its agents.[13] FDA regulations accordingly specify that manufacturers must submit "specimens of mailing pieces and any other labeling or advertising *devised for promotion of the drug product* at the time of initial dissemination of the labeling and at the time of initial publication of the advertisement for a prescription drug product."[14]

Neither the statutory language of the FDCA nor ensuing regulations provide a basis to find a manufacturer liable if a third-party not under the manufacturer's control misbrands a drug. Additionally, there appears to be no precedent for finding that independently generated

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[9] FDCA § 201(m) (defining labeling).
[10] *See, e.g.*, *Kordel v. United States*, 335 U.S. 345 (1948).
[11] *U.S. v. 24 Bottles "Sterling Vinegar & Honey*," 338 F.2d 157, 158-59 (2d Cir. 1964).
[12] *Id.*; *see also Kordel*, 335 U.S. at 351; *Founding Church of Scientology of Washington, D.C. v. United States*, 409 F.2d 1146, 1157 (D.C. Cir. 1969); *United States v. Harkonen*, 08-cv-00164 MHP, 2009 WL 1578712, at *12 (N.D. Cal. June 4, 2009) (holding there was no "integration" between the shipment of a drug product and the distribution of t-shirts allegedly containing promotional labeling). In *Kordel*, for example, the manufacturer was the source of the literature that the Supreme Court found constituted "labeling" and the manufacturer's actions were a part of "an integrated distribution program." *Kordel*, 335 U.S. at 351. The mere act of previewing or reviewing content or directing placement of promotional content does not suggest that otherwise independently generated content is "designed for use in the distribution and sale of the [product]" nor that the reviewed or previewed content is part of "an integrated distribution program." *See, e.g.*, *Founding Church of Scientology of Washington, D.C.*, 409 F.2d at 1157.
[13] Black's Law Dictionary 59 (8th ed. 2004) (defining advertising as "[t]he action of drawing the public's attention to something to promote its sale.").
[14] 21 C.F.R. § 314.81(b)(3)(i) (emphasis added). Under 21 C.F.R. § 514.80(b)(5)(ii), a manufacturer of prescription and over-the-counter new animal drugs must submit one set of specimens of mailing pieces and other labeling at the time of initial dissemination. For prescription new animal drugs, the applicant must also submit one set of specimens of any advertisement at the time of initial publication or broadcast.

content over which a firm merely has "preview or review" privilege or third-party content surrounding the firm's promotional content on a third-party site constitutes "advertising" or "labeling" under the FDCA. As written, the Draft Guidance will severely chill a manufacturer's First Amendment right of association; if a manufacturer "collaborates" with a third-party on any aspect of a third-party site, the manufacturer will become potentially responsible for all speech by that third-party. Manufacturers could then subject to burdensome regulatory requirements and the threat of criminal penalties for speech that they do not even control.[15] FDA should therefore remove the "influence" test from the Draft Guidance.

B. The "Influence" Test Is Not Supported by the Communications Decency Act, Which Expressly Prohibits Holding Web Site Hosts Responsible for Third-Party Speech

Congress has spoken to similar issues in the Communications Decency Act, 47 U.S.C. § 230 (CDA), which further demonstrates that the "influence" test is overbroad. As FDA acknowledged in the Draft Guidance, the CDA provides that "[n]o provider or user of an interactive computer service shall be treated as the publisher or speaker of any information provided by another information content provider."[16] The definition of "interactive computer service" is broad.[17] The effect of this provision is to protect internet service providers, such as entities hosting an interactive web site, blog, or chat room from liability based on the speech of third-party content providers using such forums. Courts have consistently held that providing a neutral forum does not make an internet service provider a content provider (content providers are not immune from liability based on their speech in such forums).[18] The CDA has been credited with helping make possible widely used forums such as Yelp, Wikipedia, YouTube, Facebook, and Twitter.[19]

A firm might choose to edit, preview or review content for the sole purpose of monitoring objectionably dangerous content about its products—an act specifically protected by the CDA in many circumstances, but inconsistent with FDA's proposed "influence" test.[20] Such actions would be entirely reasonable, and indeed, may help increase public safety by ensuring that potentially dangerous misinformation about the firm's products is not spread to patients. Removing such content for public safety purposes (i.e., exercising "editorial" privilege) should also not convert the remainder of the independently generated content to regulated "advertising" and "promotion."

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[15] *Cf. Elfbrandt v. Russell*, 348 U.S. 11, 17 (1966) (holding that the First Amendment forbids penalizing an individual for association with an organization that commits unlawful acts, without evidence that the individual shares the unlawful purpose or participates in unlawful activity).

[16] 47 U.S.C. § 230(c)(1) (1994).

[17] "The term 'interactive computer service' means any information service, system, or access software provider that provides or enables computer access by multiple users to a computer server, including specifically a service or system that provides access to the Internet and such systems operated or services offered by libraries or educational institutions." *Id.* at § 230(f).

[18] *Chicago Lawyers' Comm. for Civil Rights Under Law, Inc. v. Craigslist, Inc*., 519 F.3d 666 (7th Cir. 2008) (finding that as the host of a neutral forum, Craigslist was not responsible for discriminatory advertisements—it had no duty to police users' postings and was not responsible for the content of the statements posted).

[19] Electronic Frontier Foundation, "CDA Section 230: The Most Important Law Protecting Internet Speech," available at https://www.eff.org/issues/cda230 (accessed Feb. 22, 2014).

[20] 47 U.S.C. § 230(c)(2); *Zeran v. America Online, Inc.*, 129 F.3d 327 (4th Cir. 1997), *cert. denied*, 524 U.S. 937 (1998).

C. The Final Guidance Should Clarify When Manufacturers "Cause" and/or "Control" Third-Party Statements

PhRMA and its member companies believe that manufacturers should only be held responsible for promotional communications that are controlled or caused by the firm, which should be defined as content that is controlled entirely by the manufacturer or its agents and that the manufacturer or its agents are authorized to edit or delete in the manufacturer's sole discretion. For reasons already discussed, FDA cannot hold firms accountable for independent third-party statements or UGC under the FDCA; therefore, FDA should clarify when content is viewed as controlled or caused by the manufacturer in the Final Guidance. A useful way to do this would be for FDA to provide examples of situations when the manufacturer is and is not responsible for the third-party speech or UGC. For example, if an independent third-party posts a statement about an unapproved use of an approved drug for diabetes on the firm's site, the firm should not be held responsible for the content of the statement if the firm only made a neutral call for comments about diabetes.[21] Similarly, if a firm creates a discussion board inviting comments on patient experiences with diabetes, it should not be deemed to have prompted the content of the posts made by independent, third-party users.

FDA should make a clear statement that when the speaker does not control the content of UGC (e.g., independent bloggers) then the firm cannot be held responsible for their communications. Furthermore, if a firm has terms of use for its site that consist of neutral rules governing the site (e.g., no profanity) and makes edits and deletions based on the neutral terms of use, the firm should not be considered to control the content generated by independent third-parties.

III. The Final Guidance Should Recognize that Some Content on Social Media Is Not Promotional Labeling or Advertising

For enforcement purposes, once FDA determines that content is caused or controlled by a manufacturer, it must then determine whether the material may be regulated as promotional labeling or advertising under applicable statutes and regulations. The Draft Guidance proceeds on the mistaken premise that all statements about drugs on company blogs, microblogs, social networking sites, online communities, and similar forms of social media constitute labeling or advertising under the FDCA. Not all manufacturer communications, however, should be treated as promotional labeling or advertising. For example, a press release describing clinical trial results or postings on www.ClinicalTrials.gov should not ordinarily be considered promotional by FDA. The Draft Guidance will chill speech protected by the First Amendment, particularly because it is exceedingly vague.

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[21] In the Draft Guidance, FDA states that "a firm generally is not responsible for UGC that is truly independent of the firm (i.e., is not produced by, or on behalf of, or *prompted by the firm* in any particular) (emphasis added)." The phrase "prompted by the firm" is too ambiguous and does not provide firms with sufficient guidance on what type of UGC content they will be held responsible for on interactive social media. And to suggest that the mere creation of a forum with a general invitation to comment on a drug or a disease would lead to a sponsor's responsibility for everything stated in the forum as "prompted by" the sponsor would raise significant constitutional concerns. It is beyond dispute that health web sites that do not hold drug applications can create a forum for the discussion of diseases or drugs. To create liability for drug sponsors for engaging in the same activity based on the content of third-party posts and the identity of the person setting up the forum would constitute a speaker-based and content-based restriction. See *Sorrell v. IMS Health, Inc.*, 131 S. Ct. 2653 (2011) (content-based, speaker-based restrictions on speech subject to heightened scrutiny).

The premise that all online statements constitute promotional labeling or advertising is inconsistent with the FDCA. As discussed in Section II.A, the Draft Guidance ignores the limitations on the scope of the definition of "labeling" established in *United States v. Kordel*.[22] Likewise, even though the term advertising is not defined in the FDCA, the assumption that all online communications constitute advertising is inconsistent with FDA regulations. As discussed in Section II.A., the term advertising only encompasses materials devised for the *promotion* of a drug product.[23] A manufacturer may place content on social media that is not promotional in nature.

Applying this expansive interpretation of labeling and advertising in the online social media context will result in a significant chill on First-Amendment-protected speech. The FDA's definition of labeling and advertising has far-reaching consequences outside of the "postmarketing submission" rules. Under the FDA's interpretation of the Act, truthful and non-misleading speech by a sponsor about unapproved uses of drugs violates criminal prohibitions against introduction of "new drugs" and misbranding if the speech appears in a drug's "labeling" or advertising.[24] Accordingly, the Draft Guidance threatens to subject manufacturers to criminal penalties not only for *their* truthful and non-misleading speech in social media outlets under some circumstances, but also for some such statements by third-parties, in plain violation of the First Amendment.[25]

The Draft Guidance is also unconstitutionally vague because it fails to give "fair notice of conduct that is forbidden or required."[26] The Draft Guidance does not make it clear if *all* statements about a drug on social media sites constitute labeling or advertising, or if FDA would, for example, consider some types of statements to lack a sufficient "textual relationship" to a drug. Instead, it merely references regulations that are geared at traditional print media.

IV. The Final Guidance Should Not Hold Manufacturers Responsible for Speech Not Caused or Controlled By the Firm

While a firm should be responsible for comments by an employee, agent, advisor, or paid speaker acting on behalf of the firm, the Final Guidance should clarify that such agents may be speaking on their own behalf, in which case their content should be treated as independent of a manufacturer. For example, some paid speakers may be experts in therapeutic areas, and although a firm might engage a speaker to speak on the firm's behalf on occasion, the individual may frequently speak independently about his or her areas of expertise, without the firm's knowledge or control. Similarly, a firm might engage with a third-party, such as a consumer health advocate, to develop content for the firm-owned site. The health advocate may also speak independently about their specific area of interest without the firm's knowledge or control. Likewise, a firm may maintain policies, training and education for employees about appropriate use of interactive social media. Nevertheless, that employee may act outside the scope of his employment and independently post information about a personal experience with a medicine or some other event without the firm's knowledge or control. Therefore, we suggest

[22] 335 U.S. 345, 349 (1948).
[23] *See supra* note 13 & 14.
[24] *See* 21 U.S.C § 321(p), 331(a), 331(d), 352(a), 352(f), 355(a).
[25] *See United States v. Caronia*, 703 F.3d 149 (2nd Cir. 2012).
[26] *FCC v. Fox Television Stations*, 132 S. Ct. 2307, 2317 (2012).

that FDA provide examples in the Final Guidance that illustrate when an employee, agent, or paid speaker is not acting on behalf of or prompted by the firm. The firm should be responsible only for statements that it actually causes or controls. As previously discussed, it would be inappropriate to hold a firm responsible for independently generated statements—even from individuals with whom the firm has a financial or other relationship—if the firm did not cause or control the content. Under some circumstances, individuals who have a relationship with a firm should disclose that relationship, but that should not render a firm responsible for the individuals' independently generated content.

V. The Final Guidance Should Confirm that FDA Maintains Its Commitment to Protecting Online Scientific Exchange Using Social Media

The Draft Guidance states that "if an employee or agent of a firm, such as a medical science liaison or paid speaker (e.g., a key opinion leader) acting on the firm's behalf, comments on a third-party site about the firm's product, the firm is responsible for the content its employee or agent provides." The Final Guidance should confirm that this statement is not intended to signal a departure from FDA's longstanding practice to respect the free exchange of scientific ideas. The CME Guidance and related court decisions have long established the "jurisdictional line" between "[a]ctivities (programs and materials) performed by, or on behalf of, the companies that market the product" and "activities, supported by companies, that are otherwise independent from the promotional influence of the supporting company."[27] Such communication should remain free of FDA's labeling requirements if they are made on social media platforms, just as they are when made using traditional media.

VI. The Final Guidance Should Require Quarterly Activity Reports Rather than Monthly Activity Reports[28]

The Draft Guidance provides helpful recommendations for submitting interactive promotional media with Forms FDA 2253 or 2301. The approach outlined appears achievable, with a few exceptions. Quarterly submissions of an updated listing of all non-restricted sites for which a firm is responsible or for which it remains an active participant would strike a more appropriate balance between the agency's mission and burdens on industry. Given the Draft Guidance already recommends that firms submit Forms FDA 2253 or 2301 at the time of initial display and also notify the agency via general correspondence on the first day the firm ceases to be active on a site, the agency should have timely notice regarding when the firm is a participant on a particular site and when such participation ceases. Providing monthly reports including the site name, URL, date range, and cross-references to the dates of the most recent submission of the site would impose an unnecessary burden on firms and discourage firms from participating in a broad variety of interactive forums. Moreover, such reports would provide little public health benefits nor significantly assist the agency in its mission compared to quarterly reports containing the same information.

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[27] *See, e.g.*, 21 C.F.R. § 312.7(a) and CME Guidance at 64,096–99 (1997).

[28] Although the Draft Guidance provides examples and recommendations of how and when firms must submit Forms FDA 2253 or 2301, the Draft Guidance does not address how firms should submit UGC to old posts by the firm on a regular basis. For example, if a firm submits a date range for the previous month and a member of the public responds to one of the firm's posts from a few months prior, that posting will not be included in the submission. Thus, in its Final Guidance, FDA should clarify whether firms must submit this content, and if they must submit the content, how the firm should submit it to FDA.

VII. The Final Guidance Should Reflect the Fluid Nature of Interactive Social Media and State FDA Will Exercise Its Enforcement Discretion Accordingly

In the Final Guidance FDA should clarify that it intends to exercise its enforcement discretion with the understanding that interactive promotional media is frequently changing and firms may not be able to submit all of the required materials at the time of initial dissemination or may not be able to notify the appropriate FDA center on the first day the firm ceases to be active on the site. For example, the Draft Guidance states that a firm should "include annotations to describe the parts [of a site] that are interactive and allow for real-time communications" on Form FDA 2253 or 2301 submissions. A firm, however, may not be able to provide FDA with a description of "the parts [of a site] that are interactive and allow for real-time communications" at the initial time of a display of a promotion that is on a third-party web site such as Facebook. This is because the firm may not control the functionality aspects of a third-party web site and may not be responsible for any changes to the interactive sections of the site.

VIII. The Final Guidance Should Allow Firms to Satisfy the Submission Requirements for Interactive Social Media Posted on Restricted Sites by Providing FDA with Log-In Credentials to Restricted Sites if Possible

The Draft Guidance recommends that a firm submit any site for which it is responsible in its entirety on Forms FDA 2253 of 2301 at the initial time of display. However, after the initial submission or resubmission, a firm may submit an updated listing of the site that does not include screenshots or other visual representations of the actual interactive or real-time communication on Forms FDA 2253 or 2301 if the site is publically accessible without restrictions (e.g., password or subscription protected) and there are no changes to the site other than its display of real-time information. If the site is restricted, then FDA suggests that the firm continue to submit all content related to the discussion including screenshots or other visual representations of the site on a monthly basis. PhRMA recommends that FDA provide firms with the option of submitting all content related to the discussion through screenshots or other visual representations of the actual site or, as an alternative, allow the firm to provide FDA with user credentials to restricted sites rather than continuing to submit the relevant content of the restricted site in its entirety on a regular basis. This may provide FDA with a more complete review in some instances because screenshots do not always accurately capture all of the content on a dynamic interactive platform.

IX. The Final Guidance Should Clarify that the Guidance Only Applies to Interactive Social Media

PhRMA and its member companies recommend that FDA clarify whether the guidance only applies to interactive social media or if it also applies to non-interactive social media as well (e.g., banner advertisements). In Footnote 6 of the Draft Guidance FDA states: "Please note that the Agency expects that submissions of static promotional materials should remain unchanged." The example provided in this footnote is one in which the entire web site is static. The guidance is unclear as to whether static advertisements such as banner advertisements would be covered by the guidance. Applying guidance targeted at interactive social media to

non-interactive social media could be inappropriate given the unique features and characteristics of interactive social media. Thus, FDA should clarify that the Final Guidance only applies to interactive social media.

X. Conclusion

PhRMA thanks FDA for its significant efforts in providing its latest thinking in the Draft Guidance, which takes an important step toward addressing how best to regulate information about prescription drugs on the Internet and social media. PhRMA intends to continue to serve as a constructive partner on these issues and would be happy to meet with the agency to discuss the agency's regulation of online communications. Please do not hesitate to contact us if you have any questions about our comments.

Sincerely,

Jeffrey K. Francer
Vice President and Senior Counsel